CHAPTER 3
SECTION 1.6G

SIMULTANEOUS PANCREAS-KIDNEY TRANSPLANTATION

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I. PROCEDURE CODE RANGE

48170

II. POLICY

A. Preauthorized benefits are allowed for simultaneous pancreas-kidney transplantation (SPK).

1. A TRICARE Prime enrollee must have a referral from his/her Primary Care Manager (PCM) and an authorization from the Health Care Finder (HCF) before obtaining transplant-related services. If network providers furnish transplant-related services without prior PCM referral and HCF authorization, penalties will be administered according to TRICARE network provider agreements. If Prime enrollees receive transplant-related services from non-network civilian providers without the required PCM referral and HCF authorization. Managed Care Support (MCS) contractors shall reimburse charges for the services on a Point of Service basis. Special cost-sharing requirements apply to Point of Service claims. For specific information on Point of Services cost-shares and catastrophic cap calculations, see Chapter 12, Section 12.2 and Section 10.1, and Chapter 13, Section 14.1.

2. For Standard and Extra patients residing in a Managed Care Support (MCS) region, preauthorization authority is the responsibility of the MCS Medical Director, Health Care Finder or other designated utilization staff.

B. The designated preauthorizing authority shall only use the criteria contained in this policy when preauthorizing simultaneous pancreas-kidney transplantation.

C. Affirmative Patient Selection Criteria for SPK Transplantation. Benefits may be allowed for medically necessary services and supplies related to SPK transplantation when the transplantation is performed at a Medicare certified renal transplantation center, for patients who:

1. Are suffering from concomitant, Type I Diabetes Mellitus that is resistant to exogenous therapy and end stage chronic renal disease; and

2. Have exhausted more conservative medical and surgical treatments for Type I Diabetes Mellitus and renal disease.

3. Have a realistic understanding of the range of clinical outcomes that may be encountered.

4. Plans for long-term adherence to a disciplined medical regimen are feasible and realistic.

D. For a properly preauthorized patient, benefits may be allowed for medically necessary services and supplies related to SPK transplantation for:

1. Evaluation of a potential candidate's suitability for SPK transplantation whether or not the patient is ultimately accepted as a candidate for transplantation.

2. Pre- and post-transplantation inpatient hospital and outpatient services.

3. Surgical services and related pre- and postoperative services of the transplantation team.

4. The donor acquisition team, including the costs of transportation to the location of the donor organ and transportation of the team and the donated organ to the location of the transplantation center.

5. The maintenance of the viability of the donor organ after all existing legal requirements for excision of the donor organ have been met.

6. Blood and blood products.

7. FDA approved immunosuppression drugs to include off-label uses when determined to be medically necessary and generally accepted practice within the general medical community (i.e., proven).

8. Complications of the transplantation procedure, including inpatient care, management of infection and rejection episodes.

9. Periodic evaluation and assessment of the successfully transplanted patient.

E. Benefits may be allowed for Hepatitis B and pneumococcal vaccines for patients undergoing transplantation.

F. Benefits may be allowed for DNA-HLA tissue typing in determining histocompatibility.

III. POLICY CONSIDERATIONS

A. Preauthorization and retrospective authorization of SPK must meet the following two requirements:

1. Patient meets (or as of the date of transplantation, would have met) patient selection criteria; and

2. Transplantation facility is (or as of the date of transplantation, would have been) Medicare certified for renal transplantation at the time of transplantation.

B. For beneficiaries who fail to obtain preauthorization for SPK transplantation, benefits may be extended if the services or supplies otherwise would qualify for benefits but for the failure to obtain preauthorization. If preauthorization is not received, the appropriate preauthorizing authority as outlined in paragraph II.A., under Policy, is responsible for reviewing the claims to determine whether the beneficiary's condition meets the clinical criteria for the SPK transplantation benefit. Charges for transplant and transplant-related services provided to TRICARE Prime enrollees who failed to obtain PCM referral and HCF authorization will be reimbursed only under Point of Service rules.

C. Benefits will only be allowed for transplants performed at a Medicare certified renal transplantation center.

D. Claims for services and supplies related to the transplantation will be reimbursed based on billed charges until such time as a DRG is established.

E. Claims for transportation of the donor organ and transplantation team shall be adjudicated on the basis of billed charges, but not to exceed the transport service's published schedule of charges, and cost-shared on an inpatient basis. Scheduled or chartered transportation may be cost-shared.

F. Benefits will be allowed for donor costs. Refer to Chapter 3, Section 1.6L for guidelines regarding donor costs associated with organ transplantations.

G. Charges made by the donor hospital will be cost-shared on an inpatient basis and must be fully itemized and billed by the transplantation center in the name of the TRICARE patient.

H. Acquisition and donor costs are not considered to be components of the services covered under the DRG and will be reimbursed based on billed charges. These costs must be billed separately on a standard UB-92 claim form in the name of the TRICARE patient.

I. Transportation of the patient by air ambulance may be cost-shared when determined to be medically necessary. Reference Chapter 7, Section 2.1.

J. For beneficiaries who reside in TRICARE regions, the issuance of a Nonavailability Statement (NAS) shall be in accordance with the direction of the Lead Agent.

K. When a properly preauthorized candidate is discharged less than 24 hours after admission because of extenuating circumstances, such as the available organ is found not suitable or other circumstances which prohibit the transplant from being timely performed, all otherwise authorized services associated with the admission shall be cost-shared on an inpatient basis, since the expectation at admission was that the patient would remain more than 24 hours.

L. A referral and authorization is still required for TRICARE Prime enrollees who have other health insurance.

IV. EXCLUSIONS

Simultaneous kidney-pancreas transplant is excluded:

A. When any of the following contraindications exist:

1. Significant systemic or multisystemic disease (other than pancreatic-renal dysfunction) which limits the possibility of full recovery and may compromise the function of the newly transplanted organs.

2. Active alcohol or other substance abuse.

3. Malignancies metastasized to or extending beyond the margins of the kidney and/or pancreas.

4. Amputation due to vascular compromise.

B. For:

1. Expenses waived by the transplantation center (e.g., beneficiary/sponsor not financially liable).

2. Services and supplies not provided in accordance with applicable program criteria (i.e., part of a grant or research program; unproven procedure).

3. Administration of an unproven immunosuppressant drug that is not FDA approved or has not received TRICARE approval as an appropriate "off-label" drug indication. Refer to Chapter 7, Section 7.3 for TRICARE Policy requirements for immunosuppression therapy.

4. Pre- or post-transplantation nonmedical expenses (e.g., out-of-hospital living expenses, to include hotel, meals, privately owned vehicle for the beneficiary or family members).

5. Transportation of an organ donor.

V. EXCEPTIONS

A. Services and supplies for inpatient or outpatient services that are provided prior to and/or after discharge from hospitalization for a SPK performed in an unauthorized Medicare certified renal transplantation center may be cost-shared subject to applicable Program policy. Pre-admission services rendered by an unauthorized transplant center may also be cost-shared subject to applicable program policies. These exceptions are also applicable to SPKs performed prior to the effective date of October 1, 1995.

B. SPKs performed on an emergency basis in an unauthorized renal transplant facility may be cost-shared only when the following conditions have been met:

1. The unauthorized center must consult with the nearest Medicare certified renal transplant center regarding the transplantation case; and

2. It must be determined and documented by the transplant team physician(s) at the Medicare certified renal transplantation center that transfer of the patient (to a Medicare certified renal transplantation center) is not medically reasonable, even though transplantation is feasible and appropriate.

VI. EFFECTIVE DATE October 1, 1995.

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